

SEMMES MURPHEY

NEUROLOGIC & SPINE INSTITUTE

Excellence in Neuroscience

December 16, 1999

1365 S. Germantown Road
Germantown, TN 38138
901-260-0712
Fax: 901-260-0717

0821 '99 DEC 30 A10:22

Baptist Hospital - Medical Center

Neurological Surgery
Morris W. Ray, M.D.
Jerry Engelberg, M.D.
Jon H. Robertson, M.D.
Clarence B. Wardage, M.D.
Claudio A. Feler, M.D.
Keith G. Davies, M.D.
Shelly D. Timmons, M.D.
Allen K. Sils, Jr., M.D.

Pediatric Neurosurgery

Robert A. Sanford, M.D.
Michael S. Muhlbauer, M.D.
Stephanie L. Einhaus, M.D.

Neurology

Michael H. DeStazio, M.D.
Barbara L. Phillips, M.D.
William A. Pulsinelli, M.D., Ph.D.
Michael Jacowicz, M.D.
Gregory J. Condon, M.D.
Lora J. McGill, M.D.
Ronald F. Pfeiffer, Jr., M.D.
Michael C. Levin, M.D.

Physical Medicine & Rehabilitation

Margaret R. Todd, M.D.
Manuel F. Carro, M.D.

Neuropsychology

L. Keith Adams, Ph.D.
Susan R. McChesney, Ph.D.

Baptist Hospital - DeSoto

Neurology
Robert F. Goldstein, M.D.

Methodist Hospital -

**Medical Center & North
Neurological Surgery**
Joseph H. Miller, M.D.
David L. Cunningham, M.D.
James C. Morcalf, Jr., M.D.
Kevin T. Foley, M.D.
Frank D. Vioris, M.D., Ph.D.
A. Roy Tyrer, M.D.

Germantown

Neurological Surgery
Allen S. Boyd, Jr., M.D.
Joseph S. Hudson, M.D.
Glenn A. Crosby, II, M.D.
Maurice M. Smith, M.D.
Rodney G. Olinger, M.D.
Dwain E. Snyder, M.D.

Neurology

Lee S. Stein, M.D.
Lance J. Wright, M.D.
Fajru Chen, M.D., Ph.D.

Jackson, TN

Neurological Surgery
Joseph P. Rowland, M.D.
H. Glenn Barnett, M.D.
John V. Neblett, Jr., M.D.
Dirk G. Franzen, M.D.

Neurology

James H. Spruill, Jr., M.D.
Michael W. Bruggeman, M.D.
Karl E. Misulis, M.D., Ph.D.
Terri Edwards Lee, M.D.

Neuropsychology

Michael T. Anton, Psy.D.

Florence / Muscle Shoals, AL

Neurological Surgery
Roger A. Ray, M.D.
John C. Fraser, M.D.
J. Gregory Adderholt, M.D.

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

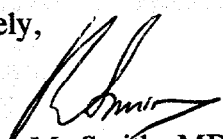
TO WHOM IT MAY CONCERN:

I have been using allograft bone for spinal fusions for over ten years. I have never had a problem with infection or rejection, secondary to the allograft. Allograft has a well established track record and has good results when appropriately placed under compression. Historically, we have had to spend much time and effort shaping allograft wedges in the operating room while our patients are laying under anesthesia with open wounds. This is at great cost to the patient. Today, however, there has been many advances in the pre-shaping of allograft tissue, which totally eliminates our need for spending time shaping the bone while the patient is under general anesthesia with an exposed spine.

These allografts are clearly not devices. They are purely allograft bone which has been cut and pre-fit to use in certain circumstances, either in the cervical, thoracic or lumbar spine. This has been a tremendous improvement in our armamentarium as it clearly reduces operative time and risks to the patient.

Pre-cut, allograft Clowered dowels have been used for over two decades without problems. I see no reason why the FDA should start regulating these sources of allograft bone as medical devices. I can only hope that you take these comments seriously and that if I may be of any further assistance in the future, please do not hesitate to call.

Sincerely,

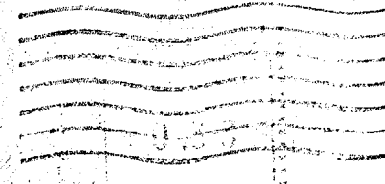
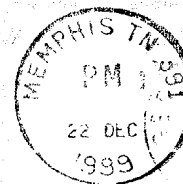

Maurice M. Smith, MD

MMS/slc

SEMMESE
MURPHEY
NEUROLOGIC & SPINE INSTITUTE
Excellence in Neuroscience

1365 South Germantown Road
Germantown, TN 38138

FORWARDING ADDRESS CORRECTION REQUEST



Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

20857+0001

